

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA
PHOENIX DIVISION

**IN RE: Bard IVC Filters Products
Liability Litigation** **MDL NO. 2641**

This Document Relates to:

TAMIKA WILLIAMS,

Plaintiff,

v.

C. R. BARD, INC., a foreign
corporation, BARD PERIPHERAL
VASCULAR, INC., an Arizona
corporation,

Case No. 2:15-cv-01956-DGC

Defendants.

ANSWER AND DEFENSES OF DEFENDANTS
C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.,
AND DEMAND FOR TRIAL BY JURY

Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”) (collectively “Defendants”) hereby file their answer and defenses to the Plaintiff’s Complaint (the “Complaint”) as follows:

THE PARTIES

1. To the extent the allegations in Paragraph 1 of the Complaint purport to cast liability upon Defendants, either directly or indirectly, those allegations are

denied. Defendants are without information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 1 of the Complaint and, on that basis, deny them.

2. Defendants deny the allegations contained in Paragraph 2 of the Complaint.

3. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the State of Georgia, including this judicial district. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Bard denies any remaining allegations contained in Paragraph 3 of the Complaint.

4. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Georgia. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademarks Recovery®, G2®, and G2®X Filter Systems. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 4 of the Complaint.

5. Paragraph 5 of the Complaint does not include any factual allegations and, as a result, requires no response by Defendants.

JURISDICTION AND VENUE

6. Defendants do not contest that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants incorporate by reference their responses to Paragraphs 1-4 of the Complaint as if fully set forth herein.

7. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which have not been and could not have been confirmed by Defendants, venue appears to be proper in this Court. Defendants admit that they are authorized to do business, and do business, in the State of Georgia, including this judicial district. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, denies them.

ALLEGATIONS

8. Defendants deny the allegations contained in Paragraph 8 of the Complaint.

9. Defendants admit that Bard owns a facility where vena cava filters are manufactured. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed,

and distributed filters under the trademark G2® Filter Systems. Defendants further admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants deny any remaining allegations contained in Paragraph 9 of the Complaint.

10. Defendants deny the allegations contained in Paragraph 10 of the Complaint, including all sub-parts thereof.

11. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 11 of the Complaint.

12. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may be designed for permanent placement, temporary placement, or both. Defendants deny any remaining allegations of Paragraph 12 of the Complaint.

13. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 13 of the Complaint.

14. Defendants admit that certain people are at an increased risk for the development of deep vein thrombosis and pulmonary embolus, but lack sufficient

information to form a belief as to the truth of the allegations as stated regarding the various risk factors which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus deny them. Defendants deny any remaining allegations of Paragraph 14 of the Complaint.

15. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 15 of the Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 15 of the Complaint and, on that basis, deny them.

16. Defendants lack knowledge or information or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market. Defendants also lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when optional or retrievable filters came to be marketed or the other allegations regarding optional or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®, G2® and G2®X Filters were cleared by the FDA for optional use as retrievable inferior vena cava filters.

Defendants deny any remaining allegations contained in Paragraph 16 of the Complaint.

17. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. The allegations pertaining to the requirements of Section 510(k) are legal conclusions of law to which no answer is required. Defendants deny any remaining allegations contained in Paragraph 17 of the Complaint, including any allegations contained in Footnote 1.

18. The allegations contained in Paragraph 18 of the Complaint are incomplete and incomprehensible. To the extent the allegations in Paragraph 18 of the Complaint purport to cast liability upon Defendants, directly or indirectly, Defendants deny such allegations.

19. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable placement on July 25, 2003, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act of 2005. Defendants deny any remaining allegations contained in Paragraph 19 of the Complaint.

20. Defendants deny the allegations contained in Paragraph 20 of the Complaint.

21. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 21 of the Complaint.

22. Defendants admit that a nickel-titanium alloy named Nitinol is used in the manufacture of the Recovery Filter and further admit that Nitinol contains shape memory. However, to the extent Paragraph 22 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

23. Defendants admit that the Recovery® Filter was designed to be inserted endovascularly. Defendants further admit that the Recovery® Filter is designed to be delivered via an introducer sheath, which is included in the delivery system for the device. Defendants deny any remaining allegations of Paragraph 23 of the Complaint.

24. Defendants deny the allegations contained in Paragraph 24 of the Complaint.

25. Defendants deny the allegations contained in Paragraph 25 of the Complaint.

26. Defendants deny the allegations contained in Paragraph 26 of the Complaint.

27. Defendants deny the allegations contained in Paragraph 27 of the Complaint.

28. Defendants deny the allegations contained in Paragraph 28 of the Complaint.

29. Defendants deny the allegations contained in Paragraph 29 of the Complaint.

30. Defendants deny the allegations contained in Paragraph 30 of the Complaint.

31. Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 31 of the Complaint, including all sub-parts thereof.

32. Defendants deny the allegations contained in Paragraph 32 of the Complaint.

33. Defendants deny the allegations contained in Paragraph 33 of the Complaint.

34. Defendants deny the allegations contained in Paragraph 34 of the Complaint.

35. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny the remaining allegations contained in Paragraph 35 of the Complaint.

36. Defendants admit that the G2®X Filter was cleared by the FDA pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny the remaining allegations contained in Paragraph 36 of Plaintiff's Complaint.

37. Defendants deny the allegations contained in Paragraph 37 of the Complaint.

38. Defendants deny the allegations of Paragraph 38 of Plaintiff's Complaint as stated. By way of further response, Defendants admit that the G2®

Filter and the G2® X Filter are identical with the exception of a modified snare tip that is added to the G2® X Filter to allow retrievability with commercially available snares.

39. Defendants deny the allegations contained in Paragraph 39 of the Complaint

40. Defendants deny the allegations contained in Paragraph 40 of the Complaint

41. Defendants deny the allegations contained in Paragraph 41 of the Complaint.

42. Defendants admit that there are various well-documented complications that may occur as a result of the fracture and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. By way of further response, Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 42 of the Complaint, including all sub-parts thereof.

43. Defendants admit that there are various well-documented complications that may occur as the result of the fracture and/or migration of any

inferior vena cava filter. Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Defendants state that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 43 of the Complaint.

44. Defendants admit that there are various well-documented complications that may occur as the result of the fracture and/or migration of any inferior vena cava filter. Defendants state that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. By way of further response, Defendants state that information available in the public domain, including the FDA MAUDE database, is not a comprehensive analysis of all instances of such complications. Defendants deny the remaining allegations of Paragraph 44 of the Complaint.

45. Defendants deny the allegations contained in Paragraph 45 of the Complaint.

46. Defendants deny the allegations contained in Paragraph 46 of the Complaint.

47. Defendants deny the allegations contained in Paragraph 47 of the Complaint.

48. Defendants deny the allegations contained in Paragraph 48 of the Complaint, including all sub-parts thereof.

49. Defendants deny the allegations contained in Paragraph 49 of the Complaint. Defendants incorporate by reference their responses to Paragraphs 19-61 of the Complaint as if fully set forth herein.

50. Defendants deny the allegations contained in Paragraph 50 of the Complaint.

51. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 51 of the Complaint and, on that basis, deny them.

52. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 52 of the Complaint.

53. Defendants deny the allegations contained in Paragraph 53 of the Complaint. Defendants incorporate by reference their response to Paragraph 1 of the Complaint as if fully set forth herein.

54. Defendants deny the allegations contained in Paragraph 54 of the Complaint.

55. Defendants deny the allegations contained in Paragraph 55 of the Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of the Complaint.

57. Some allegations contained in Paragraph 57 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 57 of Plaintiff's Complaint.

58. Defendants deny the allegations contained in Paragraph 58 of the Complaint.

59. Defendants deny the allegations contained in Paragraph 59 of the Complaint.

59 [sic]. Defendants deny the allegations contained in the second mis-numbered Paragraph 59 of the Complaint.

60. Defendants deny the allegations contained in Paragraph 60 of the Complaint.

FIRST CAUSE OF ACTION – NEGLIGENCE

61. Defendants incorporate by reference their responses to Paragraphs 1-60 of the Complaint as if fully set forth herein.

62. Defendants deny the allegations of Paragraph 62 of the Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery®, G2®, and G2®X Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery®, G2®, and G2®X Filter Systems. Defendants deny any remaining allegations contained in Paragraph 62 of the Complaint.

63. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 63 of the Complaint.

64. The allegations contained in Paragraph 64 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 64 of the Complaint.

65. Defendants deny the allegations contained in Paragraph 65 of the Complaint.

66. Defendants deny the allegations contained in Paragraph 66 of the Complaint, including all sub-parts thereof.

67. Defendants deny the allegations contained in Paragraph 67 of the Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of the Complaint.

69. Defendants deny the allegations contained in Paragraph 69 of the Complaint, including all sub-parts thereof.

70. Defendants deny the allegations contained in Paragraph 70 of the Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of the Complaint.

SECOND CAUSE OF ACTION – NEGLIGENT FAILURE TO WARN

72. Defendants incorporate by reference their responses to Paragraphs 1-71 of the Complaint as if fully set forth herein.

73. Defendants deny the allegations of Paragraph 73 of the Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery®, G2®, and G2®X Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters

under the trademarks Recovery®, G2®, and G2®X Filter Systems. Defendants deny any remaining allegations contained in Paragraph 73 of the Complaint.

74. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System was manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System.

75. The allegations contained in Paragraph 75 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 75 of the Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of the Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of the Complaint, including all sub-parts thereof.

78. Defendants deny the allegations contained in Paragraph 78 of the Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of the Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of the Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of the Complaint.

82. Defendants deny the allegations contained in Paragraph 82 of the Complaint.

**THIRD CAUSE OF ACTION – STRICT
LIABILITY FAILURE TO WARN**

83. Defendants incorporate by reference their responses to Paragraphs 1-82 of the Complaint as if fully set forth herein.

84. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark G2® Filter System.

Defendants deny any remaining allegations contained in Paragraph 84 of the Complaint.

85. Defendants deny the allegations contained in Paragraph 85 of the Complaint.

86. The allegations contained in Paragraph 86 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 86 of the Complaint.

87. Defendants deny the allegations contained in Paragraph 87 of the Complaint.

88. Defendants deny the allegations contained in Paragraph 88 of the Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of the Complaint.

90. Defendants deny the allegations contained in Paragraph 90 of the Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of the Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of the Complaint.

93. Defendants deny the allegations contained in Paragraph 93 of the Complaint.

**FOURTH CAUSE OF ACTION – STRICT
PRODUCTS LIABILITY DESIGN DEFECTS**

94. Defendants incorporate by reference their responses to Paragraphs 1-93 of the Complaint as if fully set forth herein.

95. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® Filter System. Defendants deny any remaining allegations contained in Paragraph 95 of the Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of the Complaint.

97. Defendants deny the allegations contained in Paragraph 97 of the Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of the Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of the Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of the Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of the Complaint.

**FIFTH CAUSE OF ACTION – STRICT LIABILITY
MANUFACTURING DEFECT**

102. Defendants incorporate by reference their responses to Paragraphs 1-101 of the Complaint as if fully set forth herein.

103. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark G2® Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® Filter System.

Defendants deny any remaining allegations contained in Paragraph 103 of the Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of the Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of the Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of the Complaint.

107. Defendants deny the allegations contained in Paragraph 107 of the Complaint.

SIXTH CAUSE OF ACTION – BREACH OF EXPRESS WARRANTY

108. Defendants incorporate by reference their responses to Paragraphs 1-107 of the Complaint as if fully set forth herein.

109. Defendants deny the allegations contained in Paragraph 109 of the Complaint.

110. Defendants deny the allegations contained in Paragraph 110 of the Complaint.

111. Defendants deny the allegations contained in Paragraph 111 of the Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of the Complaint.

COUNT VII – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

113. Defendants incorporate by reference their responses to Paragraphs 1-112 of the Complaint as if fully set forth herein.

114. Defendants deny the allegations contained in Paragraph 114 of the Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery®, G2®, and G2®X Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery®, G2®, and G2®X Filter Systems. Defendants deny any remaining allegations contained in Paragraph 114 of the Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of the Complaint.

116. Defendants deny the allegations contained in Paragraph 116 of the Complaint.

117. Defendants deny the allegations contained in Paragraph 117 of the Complaint.

118. Defendants deny the allegations contained in Paragraph 118 of the Complaint, including all sub-parts thereof.

119. Defendants deny the allegations contained in Paragraph 119 of the Complaint.

120. Defendants deny the allegations contained in Paragraph 120 of the Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of the Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of the Complaint.

EIGHTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

123. Defendants incorporate by reference their responses to Paragraphs 1-122 of the Complaint as if fully set forth herein.

124. Defendants deny the allegations contained in Paragraph 124 of the Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks Recovery®, G2®, and G2®X Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks Recovery®, G2®, and G2®X Filter Systems.

Defendants deny any remaining allegations contained in Paragraph 124 of the Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of the Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of the Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of the Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of the Complaint, including all sub-parts thereof.

129. Defendants deny the allegations contained in Paragraph 129 of the Complaint.

130. Defendants deny the allegations contained in Paragraph 130 of the Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of the Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of the Complaint.

NINTH CAUSE OF ACTION – FRAUDULENT CONCEALMENT

133. Defendants incorporate by reference their responses to Paragraphs 1-132 of the Complaint as if fully set forth herein.

134. Defendants deny the allegations contained in Paragraph 134 of the Complaint.

135. Defendants deny the allegations contained in Paragraph 135 of the Complaint.

136. Defendants deny the allegations contained in Paragraph 136 of the Complaint.

137. Defendants deny the allegations contained in Paragraph 137 of the Complaint.

138. Defendants deny the allegations contained in Paragraph 138 of the Complaint.

139. Defendants deny the allegations contained in Paragraph 139 of the Complaint.

**TENTH CAUSE OF ACTION –
NEGLIGENT MISREPRESENTATION**

140. Defendants incorporate by reference their responses to Paragraphs 1-139 of the Complaint as if fully set forth herein.

141. Defendants deny the allegations contained in Paragraph 141 of the Complaint, including all sub-parts thereof.

142. Defendants deny the allegations contained in Paragraph 142 of the Complaint.

143. Defendants deny the allegations contained in Paragraph 143 of the Complaint.

144. Defendants deny the allegations contained in Paragraph 144 of the Complaint.

145. Defendants deny the allegations contained in Paragraph 145 of the Complaint.

146. Defendants deny the allegations contained in Paragraph 146 of the Complaint.

147. Defendants deny the allegations contained in Paragraph 147 of the Complaint.

148. Defendants deny the allegations contained in Paragraph 148 of the Complaint.

149. Defendants deny the allegations contained in Paragraph 149 of the Complaint.

150. Defendants deny the allegations contained in Paragraph 150 of the Complaint.

**ELEVENTH CAUSE OF ACTION – FRAUDULENT
MISREPRESENTATION**

151. Defendants incorporate by reference their responses to Paragraphs 1-150 of the Complaint as if fully set forth herein.

152. Defendants deny the allegations contained in Paragraph 152 of the Complaint, including all sub-parts thereof.

153. Defendants deny the allegations contained in Paragraph 153 of the Complaint.

154. Defendants deny the allegations contained in Paragraph 154 of the Complaint.

155. Defendants deny the allegations contained in Paragraph 155 of the Complaint.

156. Defendants deny the allegations contained in Paragraph 156 of the Complaint.

157. Defendants deny the allegations contained in Paragraph 157 of the Complaint.

158. Defendants deny the allegations contained in Paragraph 158 of the Complaint.

159. Defendants deny the allegations contained in Paragraph 159 of the Complaint.

160. Defendants deny the allegations contained in Paragraph 160 of the Complaint.

161. Defendants deny the allegations contained in Paragraph 161 of the Complaint.

PUNITIVE DAMAGES ALLEGATIONS

162. Defendants incorporate by reference their responses to Paragraphs 1-161 of the Complaint as if fully set forth herein.

163. Defendants deny the allegations contained in Paragraph 163 of the Complaint.

164. Defendants deny the allegations contained in Paragraph 164 of the Complaint, including all sub-parts thereof.

165. Defendants deny the allegations contained in Paragraph 165 of the Complaint.

166. Defendants deny the allegations contained in Paragraph 166 of the Complaint.

PRAYER FOR DAMAGES

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading “PRAYER FOR DAMAGES” and beginning “WHEREFORE,” Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Further, responding to the prayer for relief as to the first cause of action for negligence against Defendants including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the second cause of action for negligent failure to warn against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the third cause of action for strict liability – failure to warn against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the fourth cause of action for strict liability – design defect against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-

parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the fifth cause of action for strict liability – manufacturing defect against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the sixth cause of action for breach of express warranty against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the seventh cause of action for breach of implied warranty of merchantability against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief

requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the eighth cause of action for breach of implied warranty of fitness for a particular purpose against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the ninth cause of action for fraudulent concealment against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the tenth cause of action for negligent misrepresentation against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the eleventh cause of action for fraudulent misrepresentation against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Defendants further deny each and every allegation not specifically admitted herein.

FIRST DEFENSE

Plaintiff's Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

SECOND DEFENSE

The sole proximate cause of Plaintiff's damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

THIRD DEFENSE

If Plaintiff has been damaged, which Defendants deny, any recovery by Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or failed to mitigate her alleged damages. To the extent Plaintiff has failed to

mitigate her alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

FOURTH DEFENSE

Plaintiff failed to exercise ordinary care for her own safety such that Plaintiff is not entitled to recover.

FIFTH DEFENSE

The injuries and damages allegedly sustained by Plaintiff may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff over which Defendants had no control.

SIXTH DEFENSE

Plaintiff's causes of action may be barred by the applicable statute of limitations and/or statute of repose.

SEVENTH DEFENSE

Plaintiff's claims are barred, in whole or in part, by the doctrines of laches, waiver, and/or estoppel.

EIGHTH DEFENSE

There was no defect in the product at issue with the result that Plaintiff is not entitled to recover against Defendants in this cause.

NINTH DEFENSE

There was no causal connection between any alleged defect in the product at issue and Plaintiff's alleged damages with the result that Plaintiff is not entitled to recover against Defendants in this cause.

TENTH DEFENSE

If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiff.

ELEVENTH DEFENSE

If Plaintiff has been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

TWELFTH DEFENSE

If Plaintiff suffered any damages or injuries, which are denied, Defendants state that Plaintiff's recovery is barred, in whole or in part, or subject to reduction under the doctrines of contributory and/or comparative negligence.

THIRTEENTH DEFENSE

In the further alternative, and only in the event that it is determined that Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune

from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

FOURTEENTH DEFENSE

If Plaintiff has been damaged, which Defendants deny, the negligence or fault of Plaintiff constitutes the sole, intervening, and superseding cause of Plaintiff's alleged damages.

FIFTEENTH DEFENSE

If Plaintiff has been damaged, which Defendants deny, the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible constitutes the sole, intervening, and superseding cause of Plaintiff's alleged damages.

SIXTEENTH DEFENSE

If Plaintiff has been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent knowledge of these persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of Plaintiff's alleged damages.

SEVENTEENTH DEFENSE

If Plaintiff has been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

EIGHTEENTH DEFENSE

If Plaintiff has been damaged, which Defendants deny, such damages were caused by abuse, misuse, user error and/or modification of the product at issue for which Defendants were and are in no way liable.

NINETEENTH DEFENSE

Defendants made no warranties of any kind, express or implied, including any alleged implied warranty of merchantability or implied warranty of fitness for a particular purpose, or any representations of any nature whatsoever to Plaintiff. To the extent applicable, Plaintiff's breach of warranty claims are barred by a lack of privity between Plaintiff and Defendants. To the extent Plaintiff makes warranty claims, whether express or implied, the claims are barred or limited by any and all express conditions or disclaimers, by Plaintiff's lack of reliance on any such warranties, and by waiver.

TWENTIETH DEFENSE

Plaintiff's claims for breach of implied warranty must fail because the product was not used for its ordinary purpose.

TWENTY-FIRST DEFENSE

Plaintiff's claim for breach of warranty is barred because Plaintiff did not first give notice of any alleged defect of the product to Defendants.

TWENTY-SECOND DEFENSE

Defendants neither had nor breached any alleged duty to warn with respect to the product, with the result that Plaintiff is not entitled to recover in this cause.

TWENTY-THIRD DEFENSE

Plaintiff's failure to warn claims are barred by virtue of the intervention of the learned intermediary or intermediaries to whom Defendants discharged their duties to warn.

TWENTY-FOURTH DEFENSE

The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetic Act, and other pertinent federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

TWENTY-FIFTH DEFENSE

Plaintiff's alleged damages resulted from independent, unforeseeable, superseding, and/or intervening causes unrelated to any conduct of Defendants.

TWENTY-SIXTH DEFENSE

If Plaintiff recovers from Defendants, Defendants are entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiff's alleged damages.

TWENTY-SEVENTH DEFENSE

Plaintiff's claims are or may be barred, in whole or in part, to the extent that Plaintiff has released, settled with, entered into an accord and satisfaction, or otherwise compromised their claims. Defendants are entitled to a set-off for the entire amount of proceeds Plaintiff has or may recover from all other sources.

TWENTY-EIGHTH DEFENSE

Should Defendants be held liable to Plaintiff, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff from all collateral sources.

TWENTY-NINTH DEFENSE

Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

THIRTIETH DEFENSE

The product at issue is neither defective nor unreasonably dangerous because it is a medical device falling within what is commonly known as Comment (j), Restatement (Second) of Torts § 402A, and comparable provisions of the Restatement (Third) of Torts (Products Liability), in that the product at issue was, at all times material to Plaintiff's Complaint, reasonably safe and reasonably fit for its intended use, and the warnings and instructions accompanying the product at the time of the occurrence or injuries alleged by Plaintiff were legally adequate.

THIRTY-FIRST DEFENSE

Plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with the generally recognized, reasonably available, and reliable state of knowledge when the product was manufactured and marketed.

THIRTY-SECOND DEFENSE

Plaintiff's claims are barred because the methods, standards, warnings, and instructions used in manufacturing and/or marketing the product at issue conformed with industry custom/usage standards and/or legislative, administrative, and/or regulatory standards.

THIRTY-THIRD DEFENSE

The design complained of in Plaintiff's Complaint, the alleged defects of the product, and/or any alternative design claimed by Plaintiff were not known and, in light of the existing, reasonably-available scientific and technological knowledge, could not have been known at the time the product at issue was designed, manufactured, and sold. Any alleged alternative design was not scientifically or technologically feasible or economically practical.

THIRTY-FOURTH DEFENSE

Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

THIRTY-FIFTH DEFENSE

No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

THIRTY-SIXTH DEFENSE

To the extent Plaintiff asserts a demand for punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm*

Mut. Auto Ins. Co. v. Campbell, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

THIRTY-SEVENTH DEFENSE

To the extent that Plaintiff asserts a claim for punitive damages, that claim is in contravention of the rights of Defendants under the following provisions of the United States Constitution and analogous provisions of the Georgia Constitutions:

Plaintiff's claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

- (a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;
- (b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes

upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

- (c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;
- (e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;
- (f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

- (g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;
- (h) the award of punitive damages to the plaintiffs in this action would constitute a deprivation of property without due process of law; and
- (i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

THIRTY-EIGHTH DEFENSE

This case may be subject to dismissal or transfer under the doctrine of forum non conveniens.

THIRTY-NINTH DEFENSE

Upon information and belief, the Summons and Complaint were not properly served on Defendant BPV under the Georgia Civil Practice Act, and Defendant BPV reserves the right to assert any defenses and/or arguments related to the improper service of the Summons and Complaint, including, *inter alia*, that this action should be dismissed pursuant to O.C.G.A. § 9-11-12(b).

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded its costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

s/Richard B. North, Jr.

Richard B. North, Jr.

Georgia Bar No. 545599

richard.north@nelsonmullins.com

Taylor T. Daly

Georgia Bar No. 697887

taylor.daly@nelsonmullins.com

Matthew B. Lerner

Georgia Bar No. 446986

matthew.lerner@nelsonmullins.com

Nelson Mullins Riley & Scarborough LLP

Atlantic Station

201 17th Street, NW / Suite 1700

Atlanta, GA 30363

PH: (404) 322-6000

FX: (404) 322-6050

**Attorneys for Defendants C. R. Bard, Inc.
and Bard Peripheral Vascular, Inc.**

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of October, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to the following attorneys of record:

R. Clay Milling II, Esq.
Henry Spiegel Milling LLP
Atlanta Plaza, Suite 2450
950 E. Paces Ferry Road NE
Atlanta, GA 30326

s/ Richard B. North, Jr. _____

Richard B. North, Jr.
Georgia Bar No. 545599